DETAILED ACTION

1. The examiner acknowledges receipt of power of attorney filed 05/03/2011; IDS filed 4/28/2011; amendment and remarks filed 3/30/2011. Claims 1, 20 and 35 are amended. Claims 2, 11, 12 and 15-19 are canceled. Claims 1, 3-7, 20, 21, 35-37, 39, 41, 43, 45 and 49 are pending. Claims 36, 37, 39, 41, 43 and 45 are withdrawn from consideration.

Response to Arguments

2. Previous objection that are not reiterated herein are withdrawn in view of the amendment.

3. Applicant's arguments, see amendment and remarks filed 3/30/2011, with respect to the rejection(s) of claim(s) 1-7, 15-21 and 35 and 49 under 35 U.S.C. 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Griesgraber (US 6,677,349) in view of Hedenstrom et al. (US 6,706,728) and Gizurarson (US 6,647980) and further in view of Kublik et al. ("Nasal delivery systems and their effect on deposition and absorption" in Advanced Drug Delivery Reviews, 29 (1998), pp. 157-177).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 3-7, 20, 21, 35 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griesgraber (US 6,677,349) in view of Hedenstrom et al. (US 6,706,728) and Gizurarson (US 6,647980) and further in view of Kublik et al. ("Nasal delivery systems and their effect on deposition and absorption" in Advanced Drug Delivery Reviews, 29 (1998), pp. 157-177).

7. Griesgraber: Griesgraber discloses composition comprising imidazoquinoline and tetrahydroimidazoquinoline compounds that contain sulfonamide or sulfonamide functionality at the 1-position are useful as immune response modifiers (abstract) in combination with pharmaceutically acceptable carrier formulated in dosage forms such as parenteral formations, syrups and aerosol formulated (column 13, lines 32-34, 47-51); one of the sulfonamide derivative of the imidazoquinoline is N-{2-[4-Amino-2-(ethoxymethyl)-1H-imidazo[4,5-c]quinolin-1-yl]-1,1-dimethyl ethyl}methanesulfonamide (example 268), which is immune response modifier of claims 1 and 35.

8. Griesgraber does not teach the carrier of the claims.

9. Hedenstrom: Hedenstrom discloses method of treating conditions associated with mucosal surface with a composition comprising immune response modifier or pharmaceutically acceptable salts of claims (abstract; column 3, lines 34-43; column 12, line 34 to column 23, line 2); the composition may contain surfactants (column 23, line 63 to column 24, line 9), viscosity enhancing agents such as carbomer/Carbopol (column 24, lines 10-19; column 8, lines 18-38), chelating agent, preservative and water (column 24, lines 20-47). The mucosal surfaces in Hedenstrom include buccal, gingival, nasal, tracheal, bronchial, gastrointestinal, rectal, urethral, urethral, vaginal, cervical, uterine, etc (column 24, line 65 to column 25, line 6). The carbopol/carbomer viscosity enhancing agents meet the limitation of claims 1 and 3-7.

10. While Hedenstrom teaches the presence of viscosity enhancing agent and while viscosity is a property of the composition, Hedenstrom does not specifically say that the formulation is administered with spray device.

11. However, Gizurarson teaches that active agents are administered to the nostrils by using nasal spray device (abstract; column 2, lines 25-51, 59, 60; column 6, line 63 to column 7, line 25) and that the nasal composition is a liquid (column 7, lines 58-60). Gizurarson also teaches that the viscosity enhancing agent should be present in such amount as to provide sufficient dynamic viscosity to the preparation in such a way that the dynamic viscosity of the composition measured at 25 ^{o}C is higher than the dynamic viscosity of water which is about 1 cP; Gizurarson then suggested that the dynamic viscosity should be at least 5 cP or in the range of 5-300 cP or 10-75 cP or 10-50 cP. A dynamic viscosity of 5 cP or 10-75 cP or 10-50 cP are all less than 100 and anticipates the recited viscosity in claim 1.

12. Furthermore, Kublik teaches that pharmaceutical nasal preparations on the market are solutions and emulsions and suspensions and are delivered by metered dose pump sprays that provides defined dose and high dosing accuracy (paragraph 4.1.5).

13. Therefore, taking the teachings of Griesgraber, Hedenstrom, Gizurarson and Kublik, one having ordinary skill in the art at the time the invention was made would be motivated to formulate the immune response modifier of Griesgraber with the carrier of Henderstrom for delivery to the mucosa by the device of Gizurarson and Kublik since the nasal spray device allows the application of defined dose with high dosing accuracy and typical spray pattern. While viscosity is an inherent property, Gizurarson discloses that the viscosity enhancing polymer should be used in amounts that would provide viscosities of 5 cP, 10-75 cP and 10-50 cP so that the claimed viscosity is rendered obvious and absent factual showing of unexpected result, a claimed viscosity of less than 100 does not patentably distinguish the disclosed viscosity of 5 cP, 10-75 cP and 10-50 cP.

14. The recitation that the "formulation is for delivery of an immune response modifier to the nasal passage of a subject" is an intended use of the formulation at the intended route of administration.

15. Prior art of Interest: Wightman et al. (US 7923560 B2) discloses composition comprising IRM such as N-{2-[4-Amino-2-(ethoxymethyl)-1H-imidazo[4,5-c]quinolin-1-yl]-1,1-dimethyl ethyl}methanesulfonamide (column 11, lines 9-11) and carrier material. However, in Wightman, the IRM is covalently attached to the polymer (abstract).

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on Monday to Thursday from 7 a.m. to 5:30 p.m.

18. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Y. Kwon can be reached on (571) 272-0581. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

19. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Primary Examiner, Art Unit 1618